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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,016	FIKSTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-33 is/are rejected.

7)☒ Claim(s) 3,5,7 and 11 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 21 March 2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are presented for examination.

Acknowledgment is made of the present application as a continuation of United States Patent Application No. 10/700,838, filed November 3, 2003. Applicant's claim under 35 U.S.C. §120 for the benefit of the filing date of U.S. Patent Application No. 10/700,838 has been considered. **In light of the fact that the presently claimed subject matter is fully supported by the disclosure of the parent application, Applicant has been granted the benefit of the parent application. The effective filing date of the present application is November 3, 2003.**

Applicant's Information Disclosure Statement (IDS) filed March 21, 2005 has been received and entered into the application. As reflected by the attached, complete copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

Objections to the Claims

Claim 3 is objected to because the word "fatty" is misspelled at line 3 of the claim.

Claims 5 and 11 are objected to because the word "nicotinate" is misspelled at line 2 of each claim.

Claim 7 is objected to for lacking antecedent basis for the term "the ester" since parent claims 1 and 3 do not recite such a limitation. See 37 C.F.R. 1.75(d)(1) and MPEP §608.01(o).

Objections to the Specification

The disclosure is objected to because of the following minor informalities:

(i) the word "fenofibrate" is misspelled at page 8, line 31 of the disclosure; the word "carvedilol" is misspelled at page 10, line 14 of the disclosure; the word "macrogolglycerides" is misspelled at page 12, line 33 of the disclosure; the word "palmitostearate" is misspelled at page 15, line 28 of the disclosure; the word "polyethylene" is misspelled at page 16, line 1 of the disclosure; the word "trehalose" is misspelled at page 19, line 9 of the disclosure; and the word "cumulative" is misspelled at page 43, line 4 of the disclosure;

(ii) the sentence ending at page 16, line 12 of the disclosure fails to conclude with a period; and

(iii) the word "nanoencapsulation" at page 16, line 22 of the disclosure should be followed by a comma, not a period.

The use of the trademarks TETRAGLYCOL or TRANSCUTOL, for example, at page 17, lines 6 and 16, respectively, has been noted in this application. Each instance should be capitalized wherever it appears and be accompanied by the generic terminology. The citation of the use of these trademarks in the present specification is not intended to be an exhaustive list of all the trademarks used within the application and does not represent all of the places at which trademarks have been improperly used. Applicant is respectfully requested to capitalize all trademarked names throughout the specification and each trademark should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 13-15, 17-19 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expressions "less than about" (claims 13-15), "more than about" (claims 17-18), "between about 2 hours and about 24 hours" (claim 19) and "less than or equal to about" (claim 30) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular aqueous solubility, time period of release or pKa is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims. Furthermore, the Examiner has noted the presence of the phrase "less than" or "more than" or "between" or "equal to" in present claims 13-15, 17-19 and 30. For example, the presence of "more than" in the phrase "more than about 1 hour" in present claim 17 indicates

that the period of time over which release is controlled is greater than 1 hour. However, the presence of the word "about" denotes that the period of time may be slightly greater or slightly less than 1 hour. Thus, it is not clear which is meant to be the limiting term. It is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims. Thus, the claims do not meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, therefore, properly rejected.

II Claims 3, 7-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The term "tocol derivative", "fatty acid derivative", "fatty alcohol derivative" or "polyoxyl castor oil derivative" in present claims 3, 7-10 and 12 are relative terms that render the claims indefinite. In particular, "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant. Applicant has failed to provide any specific definition for this term in the present specification. Lacking a clear meaning of the term "derivative", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

In the present specification at page 11, line 22-page 12, line 18, Applicant has set forth:

> "Preferred fatty acids and alcohols are the C6-C22 fatty acids and alcohols, such as stearyl alcohol, capric acid, caprylic acid, lauric acid, myristic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, behenic acid, and their corresponding pharmaceutically acceptable salts. Preferred fatty acid and fatty alcohol derivatives include sodium dioctyl sulfosuccinate...and polyglyceryl-10 mono, dioleate (Caprol® PEG 860)."

Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP §2111.01). Here, Applicants' definition, or lack thereof, of "derivative"' is not reasonably clear, deliberate or precise because the definition does not specify what other compounds may be considered tocol, fatty acid, fatty alcohol or polyoxyl castor oil derivatives. That is, the definition is presented in a non-limiting manner. Thus, the identity of those compounds that are included or excluded by the term "derivative" is open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. §112, second paragraph.

III Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what Applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph, with respect to the claimed invention." (See MPEP §2173).

In light of the guidance of MPEP §2173, which emphasizes the requirement of definiteness of claim language, the term "slowly" in the expression "slowly dissolving salt of a complex" (see claim 8, for example) and the term "high" in the expression "high molecular

weight polysaccharide gum" (see claim 10, for example) are relative terms that render the claims indefinite. The expressions are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and, thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Use of the terms "slowly" and "high" would invite subjective interpretations as to what requisite rate the dissolution of the salt would need to occur to be considered a "slowly dissolving salt" and the standard against which such dissolution is to be measured, what molecular weight of a polysaccharide gum would be considered high and the standard against which such a weight is to be measured. Thus, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims. Such subjective determinations are inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and claims 8-12 are, therefore, considered properly rejected.

IV Claim 8 is further rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The use of the phrase "insoluble carrier" is considered indefinite because Applicant has failed to delineate in what substances the carrier would be considered insoluble. The lack of a reference point in order to determine the solubility of the carrier and, thus, to determine whether a particular carrier is inside or outside the scope intended by the present claims would invite subjective interpretations of whether a carrier is considered "insoluble" because the specification and the claims have not provided a requisite standard by which such a quality is to be measured. It is the Examiner's position that the public would not be informed of the

boundaries of what constitutes infringement of the present claims. Such subjective determination is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and claim 8 is appropriately rejected.

V Claims 21-23 are also further rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The use of the phrase "correlation coefficient" is a term that renders the claim indefinite because the specification lacks a specific mathematical definition of how such a coefficient is to be calculated. Although the specification at page 8, lines 3-9, provides a verbal explanation of the "correlation coefficient", Applicant has not provided a definitive explanation as to how such a number is determined. Thus, because the specification and the claims fail to define this term or provide a standard method of calculation in order to ascertain the numerical value, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention or of what would constitute infringement of the present claims. Such subjective determinations are inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and claims 21-23 are, therefore, considered properly rejected.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-26 and 28-33 are rejected under 35 U.S.C. 102(a) or 35 U.S.C. 102(e) as being anticipated by Patel et al. (U.S. Patent No. 6,569,463 B2; 2003).

Patel et al. teaches a pharmaceutical composition comprising a variety of active ingredients, particularly pioglitazone (col.5, line 40), zafirlukast (col.5, line 3), simvastatin (col.5, line 45), atorvastatin (col.5, line 10), fenofibrate (col.5, line 25) or amiodarone (col.5, line 9), combined with a variety of surfactants "used to provide any of several advantageous characteristics to the compositions, including: increased solubility of the active ingredient in the solid carrier; improved dissolution of the active ingredient; improved solubilization of the active ingredient upon dissolution, enhanced absorption and/or bioavailability of the active ingredient...and improved stability, both physical and chemical, of the active ingredient" (col.9, line 63-col.10, line 5), including:

(1) polyoxyethylene-polyoxypropylene block copolymers (see col.20, line 29-col.21, line 24), (2) cyclodextrins and cyclodextrin derivatives (col.29, lines 29-30), (3) derivatives of fat soluble vitamins, such as vitamin E or tocopherol PEG-1000 succinate (col.23, lines 55-60) or other polyethoxylated fat-soluble vitamins or derivatives (col.24, lines 15-16), (4) glycerol fatty acid esters (col.25, line 27), (5) propylene glycol fatty acid esters (col.25, lines 56-57), (6)

sorbitan fatty acid esters (col.25, lines 49), (7) sorbitol (col.26, line 2), (8) glucose (col.32, line 35), (9) polyethylene glycol fatty acid esters (col.25, line 29), (10) lactic acid (col.31, line 33), (11) PEG-35 castor oil (Table 5, col.14, line 12; also known as CREMOPHOR EL, which Applicant has acknowledged at page 12, line 28 is equivalent to polyoxyl 35 castor oil), (12) PEG-8 caprylic/capric glycerides (Table 5, col.14, lines 63-64), (13) PEG-20 sorbitan monooleate (see Table 11, col.19, line 12; also known as polysorbate 80, which Applicant has acknowledged at page 14, lines 8-9) (13) sorbitan monooleate (see Table 16, col.21), (14) mono- or diglycerides or mixtures of mono- and diglycerides (col.25, lines 62-65) or medium or long-chain triglycerides (col.27, line 54), (15) mono- and diacetylated monoglycerides (see Table 9, col.17, lines 38-40), (16) PEG-6 corn oil (Table 5, col.14, line 42; also known as LABRAFIL M 2125 CS, which Applicant has acknowledged at page 14, lines 1-2 is equivalent to linoleoyl monoglycerides), (17) lauroyl macrogol-32-glyceride (Table 5, col.15, lines 6-7), (18) hydrogenated vegetable oils (col.24, line 28), (19) glyceryl dibehenate (see Table 19, col.27, line 22; also known as COMPRITOL 888, which Applicant has acknowledged at page 15, line 21 is equivalent to glycerol dibehenate), (20) fatty acids or fatty alcohols (col.32, lines 46-47), (21) polyglyceryl-3-distearate, (22) stearoyl macrogolglyceride (Table 5, col.14-15; also known as GELUCIRE 50/13, which Applicant has acknowledged at page 12, line 33-page 13, line 1 is equivalent to stearoyl macrogol-32 glycerides), (23) calcium/sodium stearoyl lactylate (see Table 18, col.22-23), (24) stearic acid (col.31, line 35), (25) sucrose distearate (Table 13, col.19, line 63), (26) sucrose monopalmitate (Table 13, col.20, line 8), (27) sucrose dipalmitate (Table 13, col.19, line 66) and (28) PEG-40 hydrogenated castor oil (Table 5, col.14, lines 31-32; also

known as CREMOPHOR RH40, which Applicant has acknowledged at page 12, line 27 is equivalent to polyoxyl 40 castor oil).

A variety of additives are also taught at col.30, line 62- col.32, line 61.

Patel et al. also teaches the use of polyvinylpyrrolidone (col.29, lines 39-40), hydroxypropylmethylcellulose (col.29, line 60), polysaccharides, such as acacia, tragancanth, guar and alginates, lactic acid (col.31, line 33), tannic acid (col.31, line 36), gums, such as xanthan gum, gum arabic (col.32, lines 44-45), natural or synthetic waxes, carnauba wax (col.32, lines 45-46), and shellacs, such as those based on sugars, polysaccharide-based shellacs, or cellulosic-based shellacs (col.32, lines 47-57).

Patel et al. teaches that the composition may be any one of a number of solid oral dosage forms, including a minicapsule, a capsules, a tablet, a lozenge, a wafer or a chewable tablet (col.33, lines 15-29) and that the release profile of the active ingredients can be effected by a "polymeric matrix composition, a coated matrix composition, a multiparticulate composition, a coated multiparticulate composition, an ion-exchange resin-based composition, as osmosis-based composition, or a biodegradable polymeric composition" (col.33, lines 44-49). Acrylic polymer, cellulose derivatives or polyvinyl acetate phthalate coatings may be used in the formulation of the composition (col.35, lines 4-45). The formulations of the composition discloses in Patel et al. "can be designed for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, synchronized release or targeted delayed release" (col.33, lines 35-38).

Also, because Patel et al. teaches the concept of "extended release" and "controlled release", and shows such release over a period of time that is at least 180 minutes (see, e.g., Figure 1), the claimed elements of claims 16-19 are taught by the patentees.

The Examiner cannot calculate the requirement of claims 21-23 because a mathematical formula for doing such has not been provided (see above under "Claim Rejections-35 U.S.C. Second Paragraph", Heading V). A "correlation coefficient of greater than about 0.80" or "...greater than about 0.90" or "...greater than about 0.95" is nevertheless believed to be present because in both the present claims and the reference, the same materials are employed to produce the same composition. Also, Patel et al. expressly discloses "synchronized release" at col.33, lines 37-38. Thus, it is the Examiner's position that the correlation coefficients of the patent would not differ from those presently claimed, absent factual evidence to the contrary.

Although Patel et al. does not specifically teach "a slowly dissolving salt of a complex" as recited in present claim 8, Applicant has acknowledged in the present specification that such a term, for example, indicates a complex with tannic acid at page 14, lines 20-21 of the disclosure. Tannic acid is taught by Patel et al. at col.31, line 36, as are fatty acid salts and bile salts, for example (see Table 18, col.22-23), and such disclosure, absent factual evidence or direction to the contrary, is considered to anticipate this claim limitation.

Patel et al. teaches the use of lactic acid at col.31, lines 33, which is known in the art to be synonymous with a hydroxy acid as recited in present claim 6 (see Stedman's Medical Dictionary 22nd Edition, 1973, p.595) and is, therefore, considered to anticipate this claim limitation. Furthermore, Patel et al. teaches the use of Vitamin E in the disclosed pharmaceutical composition, which is known in the art to be synonymous with alpha-tocopherol (see Stedman's

Medical Dictionary 22nd Edition, 1973, p.1400) and, therefore, is considered to anticipate the claim limitation of alpha-tocopherol in present claims 5 and 11. In concurrence with MPEP §2131.01, it is proper to rely on another reference for a rejection under 35 U.S.C. 102, provided that the additional reference is relied upon in order to explain the meaning of a term used in the primary reference.

While the Examiner has noted the limitation of "...wherein the aqueous solubility of the drug is dependent on pH" in present claim 29, such is not considered to further limit the composition of parent claim 1 because such a limitation does not impart any physical or material property to the composition that is not already present in the claim from which it depends.

Lastly, it is noted that Patel et al. is silent as to the particular aqueous solubility or pKa value of the therapeutic agent(s) of the present claims. However, absent factual evidence or direction to the contrary, it is the Examiner's position that the aqueous solubilities of the presently claimed active agents do not differ from those of the active agents of the patent.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Patent No. 6,569,463; 2003) for the reasons of record set forth above in view of Royce (U.S. Patent No. 5,403,593; 1995), Lambert et al. (U.S. Patent No. 6,458,373; 2002), Cawley et al. (U.S. Patent No. 2,680,749; 1954), Chen et al. (U.S. Patent No. 6,623,755; 2003), The Merck Index (Monograph 1882; 1989), Beatch et al. ("Ventricular Fibrillation, an Uncontrolled Arrhythmia Seeking New Targets", Drug Development Research, 2002; 55:45-52) and Julien (A Primer of Drug Action, 2001; p.510).

The differences between the Patel et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the use of glycerol palmitostearate or glycerol dipalmitate;

(ii) the use of microcrystalline wax, yellow wax, white wax, nonionic emulsifying wax, or cetyl esters wax;

(iii) the use of tocol derivatives, such as alpha-tocopherol ester, alpha-tocopherol acetate, alpha-tocopherol nicotinoate, alpha-tocopherol succinate, alpha-tocopherol polyethylene glycol succinate of various molecular weights (400 or 200-8000) and d- or dl-alpha-tocopherol polyethylene glycol 1000 succinate; and

(iv) the use of carvedilol, dronederone, risperidone or ziprasidone.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Glycerol palmitostearate and glycerol dipalmitate were well known in the art at the time of the invention as lipid components, especially useful in the preparation of sustained release pharmaceutical dosage forms (see abstract of Royce, for example, and col.4, lines 32-50). It would, therefore, have been well within the purview of a person of ordinary skill in the art at the time of the invention to use any one of glycerol palmitostearate or glycerol dipalmitate as a lipophilic surfactant in the pharmaceutical composition disclosed by Patel et al. because each would be reasonably expected to function or exert the same or similar effect as the other surfactants disclosed by the reference and would also contribute to the sustained release effect of the pharmaceutical composition.

(ii) Although Patel et al. does not expressly disclose the use of microcrystalline wax, yellow wax, white wax, nonionic emulsifying wax, or cetyl esters wax, the reference broadly teaches the use of natural or synthetic waxes at col.32, lines 45-46. However, it was well known in the art at the time of the invention that microcrystalline wax, yellow wax, white wax, cetyl esters wax and other waxes, such as avocado wax, lanolin wax or palm kernel wax, were useful in the art as wax coatings for pharmaceutical tablets (see Chen et al., col.6, lines 45-60 and col.7, lines 3-4). It would have been obvious to the skilled artisan in light of the broad teachings of Patel et al. to use other natural or synthetic waxes known in the art at the time of the invention as a component of the pharmaceutical composition disclosed in Patel et al. because each would be reasonably expected to exert the same release modulating effects as the waxes expressly taught by the reference.

(iii) The broad disclosure of Patel et al. teaches the use of Vitamin E (also known as alpha-tocopherol, see above under "Claim Rejection-35 U.S.C. 102") or derivatives, such as tocopherol polyethylene glycol 1000 succinate (col.23, lines 55-60). Although Patel et al. does not expressly teach the use of alpha-tocopherol ester, alpha-tocopherol acetate, alpha-tocopherol nicotinoate, alpha-tocopherol succinate, alpha-tocopherol polyethylene glycol succinate of various molecular weights (400 or 200-8000) and d- or dl-alpha-tocopherol polyethylene glycol 1000 succinate, alpha-tocopherol esters, including alpha-tocopherol acetate, alpha-tocopherol succinate, alpha-tocopherol nicotinoate and tocopherol polyethylene glycol succinate (also known as d-alpha-tocopherol polyethylene glycol 1000 succinate) were well known in the art at the time of the invention (see Lambert et al., col.5, lines 10-14 and col.22, lines 54-57). It would have been obvious to a person of ordinary skill in the art at the time of the invention to employ

any one or more of the known vitamin E (alpha-tocopherol) derivative compound well known in the art as a component of the pharmaceutical composition disclosed by Patel et al.

Furthermore, it would also have been well within the purview of the skilled artisan at the time of the invention to employ alpha-tocopherol polyethylene glycol succinate of varying molecular weights or various enantiomeric forms (e.g., dl-alpha-tocopherol polyethylene glycol 1000 succinate) as a component of the pharmaceutical composition disclosed by Patel et al. because these alpha-tocopherol derivatives would be reasonably expected to function in the same or similar manner and exert the same or similar effect as that of alpha-tocopherol polyethylene glycol 1000 succinate. Such tocopherol polyethylene glycol succinate compounds of, for example, molecular weights of 400-6000 or more (see Cawley et al., U.S. Patent No. 2,680,749; col.2, line 47-col.3, line 3) were well known in the art as water-soluble tocopherol derivatives and use of such would have been well within the purview of the skilled artisan for the same reasons set forth above.

(iv) Patel et al. teaches the use of antiarrhythmic agents, antihypertensive agents or anxiolytic agents as the active therapeutic agent of the disclosed pharmaceutical composition. While Patel et al. does not expressly teach the use of carvedilol, dronederone, risperidone or ziprasidone, such compounds were well known in the art at the time of the invention. The Merck Index teaches carvedilol as an antihypertensive (see Monograph 1882 at page 286), Beatch et al. teaches dronederone as an antiarrhythmic agent (see page 48, paragraph 2, lines 6-16) and Julien teaches risperidone and ziprasidone as antipsychotic agents (see page 510). The broad teaching of antiarrhythmic, antihypertensives and anxiolytics in general would have put the use of any one or more of these therapeutic agents well within the purview of the skilled artisan. Such a person

would have been motivated to use any of these agents in the disclosed composition of Patel et al. in order to enhance the therapeutic effect and also to sustain the therapeutic effect over a prolonged period of time. In particular, the skilled artisan would have appreciated that a prolonged therapeutic effect would reduce the frequency of administration of such agents, which, for a chronic condition, such as hypertension, would further enhance patient compliance with the regimen.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the composition claims of U.S. Patent Nos. 6,458,383; 6,761,903; 6,569,463; 6,294,192; 6,720,001; 6,267,985; 6,309,663; 6,383,471; 6,451,339; and 6,468,559; and are provisionally rejected over the composition claims of U.S. Patent Application Nos. 09/716,029; 10/444,935; 10/700,838; 10/428,341; 10/159,601; 10/397,969; 10/074,687;

10/322,344; and 11/031,527. This rejected is directed solely to the claims of the above-cited patents that define compositions of matter, i.e., the same statutory category of invention.

Due to the number of applicable different patents and patent applications, a detailed analysis of why the presently claimed subject matter would have been an obvious variation over each one of the applicable claims in different patents is not presented, but the rejection set forth below is applicable to all of the above-cited patents or patent applications, but for the differences in claim numbering.

Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-61 and 65-74 of U.S. Patent No. 6,294,192 and further in view of The Merck Index (Monograph 1882; 1989), Beatch et al. ("Ventricular Fibrillation, an Uncontrolled Arrhythmia Seeking New Targets", Drug Development Research, 2002; 55:45-52) and Julien (A Primer of Drug Action, 2001; p.510). For the following reasons, the presently claimed subject matter would have been obvious not only such claims, but over each of the applicable claims of the remaining U.S. Patents or U.S. Patent Applications cited above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '192 patent are not considered to be patentably distinct from each other because the present claims are clearly obvious over the patented claims. While the patented claims also recite limitations drawn to the absorbance characteristics of the composition (see patented claims

1, for example), such is not considered to impart any physical or material property to the composition, but rather is a statement of intended use. In light of such a fact, the patented claims merely require that a hydrophobic therapeutic agent in combination with a hydrophilic surfactant of the types recited in patented claims 5-20 and a hydrophobic surfactant of the types recited in patented claims 21-30 be present, since the recitation of such absorbance characteristics of the composition do not impart any patentable distinction from the composition of the present claims. The patented claims clearly provide for the use of any active therapeutic agent (see patented claims 38-42), particularly amiodarone, zafirlukast, pioglitazone, fenofibrate, atorvastatin, simvastatin or Vitamin E, surfactants and release modulators of the present claims (see patented claims 5-30, for example).

While the patented claims recite particular amounts of the surfactant components (see patented claims 2-4, for example), where the present claims are silent to specific amounts of components, the determination of the optimum amounts would have been a matter well within the purview of the skilled artisan and such a determination would have been made according to the age, sex, overall health and severity of the disease of the patient.

Furthermore, while it is acknowledged that the patented claims do not expressly recite the use of carvedilol, dronederone, risperidone or ziprasidone, but rather broadly disclose the use of antiarrhythmic agents, antihypertensive agents and anxiolytic agents, it would have been obvious to the skilled artisan to use carvedilol, a known antihypertensive, dronederone, a known antiarrhythmic or risperidone or ziprasidone, both known antipsychotics, as the active agent of the composition because such agents were well known in the art to exert these therapeutic

effects(see Monograph 1882 of The Merck Index, Beatch et al. at page 48, paragraph 2, lines 6-16 and Julien at page 510).

Moreover, the patented claims use the word "comprising", which is considered open transitional claim language and allows for the use of other components in the composition of the present claims (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the use of additional components, such as the specific types of surfactant or release modulators of the present claims, for example.

Lastly, it is noted that the patented claims recite particular solubility characteristics of the therapeutic agent (see patented claims 34-35, for example). Considering that the patented claims teach the same active agents as those of the present claims, it is the Examiner's position that the solubilities of the active agents of the present claims do not differ from those of the patented claims, absent factual evidence or direction to the contrary.

Accordingly, rejection of claims 1-33 of the present application is deemed proper over each of the above-indicated patents or patent applications as claiming obvious and unpatentable variants.

Conclusion

Rejection of claims 1-34 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096.

The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 10, 2005

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